

Drug Enforcement Administration

[Docket No. DEA-840]

Importer of Controlled Substances Application: Almac Clinical Services Incorp. (ACSI)

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Almac Clinical Services Incorp. (ACSI) has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 30, 2021, Almac Clinical Services Incorp, (ACSI) 25 Fretz Road, Souderton, Pennsylvania 18964, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

		Schedul
Controlled Substance	Drug Code	e
Psilocybin	7437	I
Oxycodone	9143	II
Hydromorphone	9150	II
Morphine	9330	II
Noroxymorphone	9668	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to import the listed finished dosage unit products controlled substances in dosage form to conduct clinical trials. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to import of the Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

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